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### VIA FEDERAL EXPRESS

April 28, 2007

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: FYI
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

CONTAIN NO CBI

RE:

TSCA Section 8(e) Notice

Dear Sir/Madam:

In accordance with the EPA's March 16, 1978 policy on Section 8(e) reporting under the Toxic Substances Control Act, and the EPA's June 1991 TSCA Section 8(e) Reporting Guide, Wolfe Brothers Face Art & FX (Wolfe) wishes to bring to your attention certain information regarding the ingredients contained in the make-up products manufacured for Wolfe.

Enclosed is a copy of the Material Safety Data Sheet (MSDS) as well as two (2) recent test reports conducted by Intertek Testing Services Taiwan Ltd. which demonstrates the products passing of USP 61 tests as conducted in accordance with FDA guidelines.

Should additional information be required by the Agency in accordance with the rule, please contact the undersigned.

Thank you in advance for you attention to this matter.

Sincerely,

Stephen J. Taormina

**CEO** 

SJT/cac ENCL

304271

# WOLFE BROTHERS FACE ART & FX, LLC Water Based Make Up / Face Paint Products (Hydrocolors)

## MATERIAL SAFETY DATA SHEET

Wolfe Brothers Face Art & FX, LLC products are manufactured in accordance with FDA and European Union guidelines. Wolfe products conform to the USA ASTM D 4236 and European 76/768/EEC. The components and end resulting products are just as safe to use on the face and body as any good cosmetic. The ingredients meet cosmetic guidelines for both the United States and European Community and are designed to be used on children and adults.

The data presented in this "Material Safety Data Sheet" represents the safety information on each component of our products. The components, as a final commodity, are stable, easy on the skin, and wash off with soap and water. Make-up can also be removed using petroleum jelly or baby oil.

Like most make-up, dark colors on some people may leave a bit of residue on the skin for a few hours after washing. This also depends on how long the make-up remains on the skin and the type of complexion of the person. The FDA recommends that all red make-up be kept at least one half inch from eyes.

## PRODUCT INGREDIENTS

## **Water Based Products**

Our products contain some or all the following ingredients: Calcium Carbonate, Paraffin Wax, Petrolatum, Dextrin, Glycerin, Stearyl Alcohol, Water, Acacia Senegal Gum, Sodium Benzoate, Disodium EDTA, Perfume and Pigments.

		Products (	Contain All of The	se Ingredients		
PRODUCT NAME	FORMULA	HEALTH	FLAMMABILITY	REACTIVITY	FIRST AID MEASURES	CAS Number
Calcium Carbonate	CaCO	0	0	0	A	CAS# 471-34-1 EINECS# 207-439-9
Paraffin Wax	N/A	0	1	0	С	CAS# 8002-74-2 EINECS# 232-325-6
Petrolatum	N/A	1	1	0	С	CAS# 8009-03-8 EINECS# 232-373
Dextrin	(C6H10O5)n.xH2O	1	1	0	С	CAS# 9004-53-9 EINECS# 232-675-4
Glycerin	N/A	1	0	0	D	CAS# 56-81-5 EINECS# 200-289-5
Stearyl alcohol	С18-Н37-ОН	1	1	0	A	CAS# 112-92-5 EINECS# 204-017-6
Water	H2O	0	0	0	N/A	CAS# 7732-18-5 EINECS# 231-791-2
Acacia Senegal Gum	C18H38O	1	1	0	Н	CAS# 9000-01-5 EINECS# 232-519-5
Sodium Benzoate	C7-H5-O2-Na	2	1	0	Н	CAS# 532-32-1 EINECS 206-534-8
Disodium EDTA	C10H14N2O8Na2 • 2H2O	0	1	0	В	CAS# 6381-92-6 EINECS# 205-358-3
Perfume- Musk RO 7562 (Trace)	Hydroxy- methylpentylcyclo- hexenecarboxaldehyde	N/A	N/A	N/A	G	CAS# 31906-04-4 EINECS# 250-863-4
Hazard Rating: Least Slight Moderate High Extreme						
		0	1 2	34		

## **CONTINUED**

# WOLFE BROTHERS FACE ART & FX, LLC Water Based Make Up / Face Paint Products (Hydrocolors)

Wolfe Brothers' color additives are strictly regulated. In order to protect consumers from harmful contaminants, some colors require FDA certification. These colors come from batches that are certified by FDA. Each batch is provided with its own individual certification lot number. Our color additives meet FDA color additive guidelines and the European Cosmetic Products 76/768/EEC Council Directive. Non-Toxic Fluorescent Pigments are used in some colors. Our Products will contain one or more of these ingredients.

	TECHNICAL INFORMATION on COLOR ADDITIVES					
United States FDA name	European Cl Number	Japanese name	Color Index name	CAS#:	General name	
D & C Red No.27	C.I. 45410	Red No.218	Solv. Red 48	13473-26-2	Tetrachlorotetrabromofluorescein	
D & C Red No.7 & No.6	CI 15850 CI 15850-1	Red No 202	Pig Red 57	5281-04-9	Red Number6 / 7 Lake	
FD & C Blue No.1	C.I. 42090	Blue No.1	Food Blue 2	3844-45-9	Brilliant Blue	
FD & C Blue No.4	C.I. 42090	Bleu 204	Food Blue 4	3844-45-9	Acid Blue 6	
D & C Black 2	C.I. 77266	Carbon Black	Pigment Black 6	1333-86-4	Carbon Black	
FD & C Yellow No.5		Yellow No.4	Acid Yellow 23	1934-21-0	Tartrazine	
Ultramarines	CI 77007	Ultramarine	Ultramarine	57455-37-5	Ultramarine	
Ferric Ferrocyanide	CI 77510	Ferric Ferrocyanide	Pigment Blue 27	14038-43-8	Ferric Ferrocyanide	
Iron Oxides	CI 77491	Red Oxide of Iron	Iron Oxide	1309-37-1	Iron Oxides (Red)	
Titanium Dioxide	CI 77891	Titanium Dioxide	Pigment White 6	13463-67-7	Titanium Dioxide	
Mica	CI 77019	Mica	Mica	12001-26-2	Mica	
Bismuth Oxychloride	CI 77163	Bismuth Oxychloride	Bismuth Oxychloride	7787-59-9	Bismuth Oxychloride	

## FDA COLOR ADDITIVES FACT SHEET

U. S. Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Cosmetics and Colors Fact Sheet July 30, 2001

## COLOR ADDITIVES FACT SHEET

Color additives have long been a part of human culture. Archaeologists date cosmetic colors as far back as 5000 B.C.

The FDA separates color additives into two categories. These are colors that the agency certifies (derived primarily from petroleum and known as coal-tar dyes) and colors that are exempt from certification (obtained largely from mineral, plant, or animal sources). Only approved substances may be used to color foods, drugs, cosmetics, and medical devices.

The FDA requires domestic and foreign manufacturers of certain colors to submit samples from each batch of color produced. FDA scientists test each sample of these colors to confirm that each batch of the color is within established specifications. These certified colors are listed on labels as FD&C, D&C or external D&C. Using the uncertified versions of color additives that require certification is illegal in foods, drugs, cosmetics, and medical devices.

The color certification program is self-supporting because the law requires manufacturers to pay FDA a user fee for each pound of color the agency certifies. In Fiscal Year 2000 FDA certified more than 13 million pounds of color additives.

For further information contact: Wolfe Brothers Face Art & FX, LLC. Tel 407-895-9971 www.wolfefx.com

Updated: 04/31/07

### FIRST AID RECOMMENDATIONS

	Generally not hazardous in normal handling, however good laboratory practices should always be used. Avoid long-term					
	exposure to skin or by inhalation.					
*	FIRST AID:					
	SKIN: Wash exposed area with soap and water. If irritation persists, seek medical attention.					
A	EYES: Wash eyes with plenty of water for at least 15 minutes, lifting lids occasionally. Seek medical attention.					
<b>A</b>	INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.					
	INGESTION: If swallowed, induce vomiting immediately after giving two glasses of water. Never give anything by mouth to					
	an unconscious person					
	Generally not hazardous in normal handling, however good laboratory practices should always be used. Avoid long-term					
	exposure to skin or by inhalation.					
	FIRST AID:					
B	SKIN: Immediately flush skin with plenty of soap and water for at least 15 minutes. Remove contaminated clothing and shoes.					
	Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention if irritation develops.					
	EYES: Wash eyes with plenty of water.					
	INHALATION: Remove to fresh air. Get medical attention for any breathing difficulty.					
	INGESTION: Not expected to require first aid measures. If large amounts were swallowed, give water to drink and get medical					
	advice.					

. •	Generally not hazardous in normal handling, however good laboratory practices should always be used. Avoid long-term exposure to skin or by inhalation.
	FIRST AID:
	SKIN: Wash exposed area with soap and water. If irritation persists, seek medical attention.
	EYES: Wash eyes with plenty of water for at least 15 minutes, lifting lids occasionally. Seek medical attention.
<b>C</b>	NHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
	INGESTION: Give several glasses of milk or water. Vomiting may occur spontaneously, but it is not necessary to induce.
	Never give anything by mouth to an unconscious person.
	Generally not hazardous in normal handling, however good laboratory practices should always be used. Avoid long-term
	exposure to skin or by inhalation.
	FIRST AID:
ļ	SKIN: Wash exposed area with soap and water. If irritation persists, seek medical attention.
	EYES: Wash eyes with plenty of water for at least 15 minutes, lifting lids occasionally. Seek medical attention.
D	INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
	INGESTION: Give several glasses of milk or water. Vomiting may occur spontaneously, but it is not necessary to induce.
	Never give anything by mouth to an unconscious person.
	Generally not hazardous in normal handling, however good laboratory practices should always be used. Avoid long-term
-	exposure to skin or by inhalation.
E	FIRST AID:
	SKIN: Not expected to require first aid measures.
	EYES: Wash thoroughly with running water. Get medical advice if irritation develops.
	INHALATION: Not expected to require first aid measures.
	INGESTION: If large amounts were swallowed, give water to drink and get medical advice.
	Generally not hazardous in normal handling, however good laboratory practices should always be used. Avoid long-term
17	exposure to skin or by inhalation.
F	FIRST AID:
	SKIN: Not expected to require first aid measures.
	EYES: Flush eyes with water for at least 15 min. See physician if irritation persists.
	INHALATION: Remove to fresh air. If breathing is difficult give oxygen. See physician.
	INGESTION: None needed for small amounts. For large amounts, if conscious, give milk to drink, induce vomiting, and call
ļ	physician.
	Generally not hazardous in normal handling, however good laboratory practices should always be used. Avoid long-term
G	exposure to skin or by inhalation.
G	FIRST AID:
	SKIN: In case of contact, immediately wash skin with plenty of soap and water for at least 15 minutes.
	EYES: In case of eye contact, immediately flush with plenty of water for at least 15 minutes.
	INHALATION: If a person breathes in large amounts, move the exposed person to fresh air.
<u> </u>	INGESTION: If large amounts were swallowed, give water to drink and get medical advice.
	Generally not hazardous in normal handling, however good laboratory practices should always be used. Avoid long-term
H	exposure to skin or by inhalation. FIRST AID:
	SKIN: In case of contact, immediately wash skin with plenty water for at least 15 minutes.
	EYES: In case of eye contact, immediately flush with plenty of water.
	INHALATION: If a person breathes in large amounts, move the exposed person to fresh air.
	INGESTION: Do not induce vomiting unless directed by medical personnel.



TEST REPORT

NUMBER : THJ0031023

LUCKY ART INDUSTRIAL CO., LTD. DATE : OCT 03, 2006 APPLICANT:

NO 7 TE-HSING 6RD SU-AO 270 I-LAN

TAIWAN ROC

SAMPLE DESCRIPTION:

ONE (1) SET OF SUBMITTED SAMPLE SAID TO BE :

ITEM NAME

: AQUA BODY CRAYONS & PAINT

: 1 SET QUANTITY

COUNTRY OF ORIGIN : CHINA & TAIWAN DATE SAMPLE RECEIVED : SEP 26, 2006 DATE TEST STARTED : SEP 28, 2006

TEST CONDUCTED:

AS REQUESTED BY THE APPLICANT, FOR DETAILS PLEASE REFER TO ATTACHED PAGE.

\*

CONCLUSION:

TESTED SAMPLE STANDARD RESULT SUBMITTED SAMPLE TOTAL PLATE COUNT PASS

> - AS PER APPLICANT'S REQUEST WITH REFERENCE TO BAM, 8TH EDITION, REVISION 2001 BY FDA

AUTHORIZED BY: ON BEHALF OF INTERTEK TESTING SERVICES TAIWAN LIMITED

JACOB LIN GENERAL MANAGER THIS REPORT SHALL NOT BE REPRODUCED EXCEPT IN FULL, WITHOUT THE WRITTEN APPROVAL OF THE LABORATORY.

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NUMBER: THJ0031023

TEST CONDUCTED

#### TOTAL PLATE COUNT

AS PER APPLICANT'S REQUEST WITH REFERENCE TO BACTERIOLOGICAL ANALYTICAL MANUAL (BAM),  $8^{\text{TH}}$  EDITION, REVISION 2001, BY FDA.

TESTED SAMPLE (1/2/3/4/5/6/7/8/9/ 10/11/12) RESULT 30 CFU/g <u>LIMIT #</u> < 5000 CFU/g

REMARKS : CFU = COLONY FORMING UNIT

# = THE LIMIT IS ACCORDING TO CTFA'S (COSMETICS, TOILETRY AND FRAGRANCE ASSOCIATION) TECHNICAL GUIDELINE.

#### TEST COMPONENTS:

- (1) WHITE BODY CRAYONS & PAINT
- (2) YELLOW BODY CRAYONS & PAINT
- (3) ORANGE BODY CRAYONS & PAINT
- (4) YELLOW OCHER BODY CRAYONS & PAINT
- (5) LIGHT GREEN BODY CRAYONS & PAINT
- (6) RED BODY CRAYONS & PAINT
- (7) DARK GREEN BODY CRAYONS & PAINT
- (8) BLUE BODY CRAYONS & PAINT
- (9) NAVY BODY CRAYONS & PAINT
- (10) BROWN BODY CRAYONS & PAINT
- (11) PURPLE BODY CRAYONS & PAINT
- (12) BLACK BODY CRAYONS & PAINT

END OF REPORT



TEST REPORT

NUMBER: THJ0042236

APPLICANT: LUCKY ART INDUSTRIAL CO., LTD. DATE : APR 03, 2007

NO 7 TE-HSING 6RD SU-AO 270 I-LAN

TAIWAN ROC

SAMPLE DESCRIPTION:

ONE (1) GROUP OF SUBMITTED SAMPLE SAID TO BE :

ITEM NAME

: FACE PAINT

ITEM NO.

: FS-6

COLOR

: GREEN, BLUE, YELLOW, RED, WHITE, BLACK

OUANTITY

: 1 GROUP

COUNTRY OF ORIGIN

: TAIWAN & CHINA

DATE SAMPLE RECEIVED

: MAR 23, 2007

DATE TEST STARTED

: MAR 26, 2007

TEST CONDUCTED:

AS REQUESTED BY THE APPLICANT, FOR DETAILS PLEASE REFER TO ATTACHED PAGE. \*

CONCLUSION:

TESTED SAMPLE

STANDARD

RESULT

SUBMITTED SAMPLE

MICROBIAL LIMIT TESTS

PASS

- WITH REFERENCE TO UNITED STATES PHARMACOPEIA XXVII <61> AND ASTM

F963-03 SECTION 4.3.6.3 \*

AUTHORIZED BY: ON BEHALF OF INTERTEK TESTING SERVICES TAIWAN LIMITED



K. Y. LIANG DIRECTOR

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NUMBER: THJ0042236

TEST CONDUCTED

### MICROBIAL LIMIT TESTS

WITH REFERENCE TO UNITED STATES PHARMACOPEIA XXVII <61> AND ASTM F963-03 SECTION 4.3.6.3.

		RESULT	LIMIT
		(1)/(2)/(3)/(4)/	
		(5)/(6)	
(a)	TOTAL AEROBIC MICROBIAL COUNT	<10 CFU/g#	(a)+(b)SHOULD BE
(b)	MOULD AND YEAST COUNT	<10 CFU/g#	£5000 CFU/g
(c)	Staphylococcus aureus	ABSENT	ABSENT
(d)	Pseudomonas aeruginosa	ABSENT	ABSENT
(e)	SALMONELLA	ABSENT	ABSENT
(f)	Escherichia coli	ABSENT	ABSENT

ITEM (a) AND (b) ARE RECOMMENDED AS TOTAL VIABLE COUNT. WITH REFERENCE TO CTFA MICROBIOLOGY GUIDELINES, THE MICROBIOLOGICAL LIMITS WERE AS FOLLOWS:

	TOTAL VIABLE COUNT		
CATEGORY	RECOMMENDED	ACCEPTANCE	
	LIMIT	LIMIT	
-BABY PRODUCTS	100 CFU/g	500 CFU/g	
-EYE AREA PRODUCTS	100 CFU/g	500 CFU/g	
-COSMETICS, TOILETRIES AND OTHER PRODUCTS	1000 CFU/g	5000 CFU/g	

REMARKS: CFU = COLONY FORMING UNIT

# = NO COLONY WAS DETECTED AT THE ONE-TENTH DILUTION OF THE

SAMPLE

£ = LESS THAN AND EQUAL TO

#### TEST COMPONENTS:

- (1) GREEN COLOR FACE PAINT
- (2) BLUE COLOR FACE PAINT
- (3) YELLOW COLOR FACE PAINT
- (4) RED COLOR FACE PAINT
- (5) WHITE COLOR FACE PAINT
- (6) BLACK COLOR FACE PAINT

END OF REPORT

\*